

**Radiation-generating Equipment Committee (REC)
November 20, 2009
Approved Minutes**

MEMBERS PRESENT

Chuck Wissuchek
Jack Dukes
Thomas Hangartner
Ruth Hackworth
Kathryn Gardner

MEMBERS ABSENT

Lawrence Osher, Chair
Kerry Krugh, Vice Chair
Sally Baden
Teresa Yates
Nina Kowalczyk
Brenda Johnson
Mary Ann Accorinti

GUESTS

Jill Paessun, Mt. Carmel Health System
Susan Suchan, Mt. Carmel Health System
Thavendra Rajah, Mt Carmel
Nelundu Gupta, James Cancer

ODH ATTENDEES

Margie Wanchick
James Castle
David Lipp

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The Radiation-generating Equipment Committee (REC) meeting was called to order by Margie Wanchick at 10:20 a.m. The meeting was held at the Ohio Department of Health (ODH) in the 7th Floor Large Conference Room at 246 North High Street, Columbus, Ohio. The Sign-in Sheet serves as the Roll Call and official record of attendance.

Past Minutes: The committee reviewed the October 23, 2009 minutes. Jack Dukes made a motion to accept the minutes with adding one edit (i.e., an additional sentence in the paragraph regarding the Quality Management Program Rule 67-04.) Ruth Hackworth seconded it, and the members present unanimously approved the motion.

Old Business:

Status of Rules

Margie Wanchick distributed and explained the X-ray Rule Status Log specifically developed for tracking progress of the new Chapter 3701:1-67 therapy rules. Margie noted that the following terms are on her list to possibly be defined in new rule 3701:67-01 **Definitions:** 1) written directive; 2) treatment chart; 3) dose (administered or prescribed); 4) wrong treatment site; 5) wrong patient; and 6) plan objective.

New Business:

The committee reviewed the comments they prepared for the **General Technical Requirements Rule 3701:1-67-03**. Several edits were recommended and will be included in the updated draft rule which will become a permanent part of these minutes. Chuck Wissuchek asked for clarification about paragraph (H), specifically, the intent of the “independent survey” requirement, noting that it is not in the current rules. Margie will research and report back to the committee at the next meeting.

Margie distributed and explained that the version of **rule 3701:1-67-12** being reviewed today was created and modeled after the reporting requirements found in SSR Part X..5.b and will allow ODH and this committee to be consistent in comparing radiation therapy standards. The title of the rule was changed to **Reports and Notifications of Misadministrations**. Margie explained that the term used

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for reporting as it relates to radioactive materials is “medical events.” Likewise, “incident” is the term currently used in Health Care Facilities (HCF) rule 3701-83-47 and Health Care Services (HCS) rule 3701-84-71. The rule draft was reviewed and edits were made; the edited version will become a permanent part of these minutes.

The review of the new **Calibration of Survey Instruments rule 3701:1-67-07** began. Several clarification edits were suggested to paragraph (B). The edited version will become a permanent part of these minutes.

Edits suggested from the last meeting regarding the **General Administration Requirements rule 3701:1-67-02** were reviewed. Margie noted that she added a new paragraph (K), providing for the variance option which was absent from the original draft. No other changes were suggested. This edited version will become a permanent part of these minutes.

Edits suggested from the last meeting regarding the **Quality Management Program rule 3701:1-67-04** were reviewed. One edit was necessary in paragraph (C)(4). The edited version will become a permanent part of these minutes.

Future Meeting Date: January 8, 2010

Adjourn: The meeting was adjourned at approximately 3:00 p.m.

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3701:1-67-02 General Administrative Requirements.

- (A) The handler shall be responsible for directing the operation of the therapy equipment. The handler shall ensure that the requirements of this Chapter are met in the operation of the therapy equipment.
- (B) Therapy equipment that does not meet the provisions of rules within Chapter 3701:1-67 of the Administrative Code shall not be used for irradiation of patients.
- (C) For any therapy equipment subject to rules 3701:1-67-05 or 3701:1-67-06 of the Administrative Code, the handler shall require the physician who authorizes use of the therapy equipment to be:
 - (1) Certified in one of the following:
 - (a) Radiation oncology or therapeutic radiology by the “American Board of Radiology or Radiology,” or combined diagnostic and therapeutic radiology program by the “American Board of Radiology” prior to 1976; or
 - (b) Radiation oncology by the “American Osteopathic Board of Radiology;” or
 - (c) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology;” or
 - (d) Therapeutic radiology by the “Canadian Royal College of Physicians and Surgeons;” or
 - (e) Radiation oncology by the “American College of Veterinary Radiology.”
 - (2) In active practice of therapeutic radiology, and has completed two hundred hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, five hundred hours of supervised work experience, and a minimum of three years of supervised clinical experience.
 - (a) To satisfy the requirement for instruction, the classroom and laboratory training shall include:
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;

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- (iii) Mathematics pertaining to the use and measurement of ionization radiation; and
 - (iv) Radiation biology.
- (b) To satisfy the requirement for supervised work experience, training shall be under the supervision of a board certified authorized user who meets the qualifications of paragraph (C)(1) of this rule, and shall include:
- (i) Review of the full calibration measurements and periodic quality assurance checks;
 - (ii) Evaluation of prepared treatment plans and calculation of treatment times/patient treatment settings;
 - (iii) Using administrative controls to prevent misadministrations;
 - (iv) Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and
 - (v) Checking and using radiation survey meters.
- (c) To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the “Residency Review Committee” for “Radiology of the Accreditation Council for Graduate Medical Education” or the “Committee on Postdoctoral Training” of the “American Osteopathic Association” and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:
- (i) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations or contraindications;
 - (ii) Selecting proper dose and how it is to be administered;
 - (iii) Calculating the therapeutic radiation machine doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by patients' reaction to radiation; and
 - (iv) Post-administration follow-up and review of case histories.

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- (D) For any therapy equipment subject to rules 3701:1-67-05 or 3701:1-67-06 of the Administrative Code, the handler shall require the qualified medical physicist to:
- (1) Be certified by the “American Board of Radiology” in one of the following:
 - (a) Therapeutic radiological physics;
 - (b) Roentgen-ray and gamma-ray physics;
 - (c) X-ray and radium physics;
 - (d) Radiological physics; or
 - (2) Be certified by the “American Board of Medical Physics in Radiation Oncology Physics;” or
 - (3) Be certified by the “Canadian College of Medical Physics;” or
 - (4) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university, and have completed one year of full time training in medical physics and an additional year of full time work experience under the supervision of a board certified medical physicist who meets the qualifications of paragraph (D)(1), (D)(2) or (D)(3) of this rule at a medical institution. This training and work experience shall be conducted in clinical radiation facilities that provide high-energy external beam radiation therapy with photons and electrons with energies greater than or equal to one MV/one MeV. To meet this requirement, the individual shall have performed the tasks listed in rules 3701:1-67-03, 3701:1-67-05, and 06 of the Administrative Code under the supervision of a qualified medical physicist during the year of work experience.
 - (5) Notwithstanding the provisions of this rule, certification pursuant to paragraphs (D) (1) to (D)(3) of this rule for all persons currently qualifying as a qualified medical physicist pursuant to paragraph (D)(4) of this rule.
- (E) Every individual who performs radiation therapy procedures on human beings shall be a licensed practitioner or hold a valid radiation therapist license as required by Chapter 3701-72 of the Administrative Code. The names and training of all personnel currently operating therapy equipment shall be kept on file at the facility. Information on former operators shall be retained for a period of at least two years beyond the last date they were authorized to operate the therapy equipment at that facility.

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- (F) Written safety procedures and rules shall be developed by a qualified medical physicist and shall be available in the control area of the therapy equipment, including any restrictions required for the safe operation of each piece of therapy equipment. The operator shall be able to demonstrate familiarity with these rules.
- (G) Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a physician authorized to use the therapy equipment. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-medical purposes.
- (H) All individuals associated with the operation of therapy equipment shall be instructed in and shall comply with the provisions of the handler's quality management program. In addition to the requirements of this chapter of the Administrative Code, these individuals are also subject to the applicable requirements of Chapter 3701:1-38 of the Administrative Code.
- (I) The handler shall maintain the following information in a separate file or package for each piece of therapy equipment, for inspection by the department:
 - (1) Report of acceptance testing;
 - (2) Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by Chapter 3701:1-67 of the Administrative Code, as well as the names of people who performed such activities;
 - (3) Records of maintenance and/or modifications performed on each piece of therapy equipment, as well as the names of people who performed such services;
 - (4) Signature of person authorizing the return of the therapy equipment to clinical use after service that affects patient treatment, or after repair or upgrade.
- (J) All records required by Chapter 3701:1-67 of the Administrative Code shall be retained until disposal is authorized by the department unless another retention period is specifically authorized in rules found within this chapter. All required records shall be retained in an active file from at least the time of generation until the next department inspection. Any required record generated prior to the last department inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved until such time as the department authorizes final disposal.
- (K) The director may, upon application thereof or upon his or her own initiative, grant a variance to the requirements of this rule as he or she determines is authorized by law, provided that the handler shows to the satisfaction of the

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director that there is good cause for the variance, and that the variance shall not result in any undue hazard or effect on the public health and safety. The terms, conditions, and expiration of the variance shall be set forth in writing by the director. Failure to comply with the terms of the variance may result in immediate revocation of the variance.

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3701:1-67-03 General Technical Requirements

(A) The handler shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed are performed by a qualified medical physicist with an operable radiation measurement survey instrument calibrated in accordance with rule 3701:1-67-07 of the Administrative Code.

(B) The radiation protection survey shall be performed by, or under the direction of, a qualified medical physicist.

(C) With the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation, and with the therapeutic radiation machine in a "BEAM-ON" condition, the qualified medical physicist shall verify that:

(1) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in rule 3701:1-38-12 of the Administrative Code; and

(2) Radiation levels in unrestricted areas do not exceed the limits specified in 3701:1-38-13 of the Administrative Code.

(D) In addition to the requirements of paragraphs (A) through (C) of this rule a radiation protection survey shall also be performed prior to any subsequent medical use and:

(1) After making any change in the treatment room shielding;

(2) After making any change in the location of the therapeutic radiation machine within the treatment room;

(3) After relocating the therapeutic radiation machine; or

(4) Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

(E) The survey record shall indicate:

(1) all instances where the facility, in the opinion of the qualified medical physicist, is in violation of applicable regulations;

(2) The date of the measurements;

(3) The reason the survey is required;

(4) The manufacturer's name, model number and serial number of the therapy equipment;

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- (5) The manufacturers' names, model numbers, serial numbers and dates of calibration of the instruments used to measure radiation levels and its calibration date;
 - (6) A plan of the areas surrounding the treatment room that were surveyed;
 - (7) The measured dose rate at several points in each area expressed in microsieverts or millirems per hour;
 - (8) The calculated maximum level of radiation over a period of one week for each restricted and unrestricted area; and
 - (9) The signature of the individual responsible for conducting the survey;
- (F) If the results of the surveys required by paragraphs (A) through (D) of this rule indicate any radiation levels in excess of the respective limits, the handler shall lock the control in the "OFF" position and not use the unit:
- (1) Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or
 - (2) Until the handler has received a specific exemption from the department.
- (G) If the survey required by this rule indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by rules 3701:1-38-12 and 13 of the Administrative Code, before beginning the treatment program the handler shall:
- (1) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with rules 3701:1-38-12 and 13 of the Administrative Code;
 - (2) Perform the survey required by paragraph (D) of this rule; and
 - (3) Include in the report required by paragraph (I) of this rule and the results of the initial survey, a description of the modification made to comply with paragraph (G)(1) of this rule, and the results of the second survey; or
 - (4) Request and receive a variance from the department as authorized under paragraph (Y) of rule 3701:1-67-02(K) of the Administrative Code that authorizes radiation levels in unrestricted areas greater than those permitted by rules 3701:1-38-12 and 13 of the Administrative Code.
- (H) The handler shall have a calibrated primary dosimetry system available for use. The system shall have been calibrated by the National Institute for Standards and Technology

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(NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within the previous twenty-four months and after any servicing that may have affected system calibration.

(1) For beams with energies greater than 1 MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt-60;

(2) For beams with energies equal to or less than 1 MV (1 MeV), the dosimetry system shall have been calibrated at an energy (energy range) appropriate for the radiation being measured;

(I) The handler may have a secondary dosimetry system for quality assurance check measurements available for use. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (H) of this rule. This comparison shall have been performed within the previous twelve months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in paragraph (H) of this rule.

(J) The handler shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the registration. For each calibration, intercomparison, or comparison, the record shall include:

(1) The date;

(2) The manufacturers' names, model numbers and serial numbers of the instruments that were calibrated, inter-compared, or compared as required by paragraphs (H) and (I) of this rule;

(3) The correction factors that were determined;

(4) The names of the individuals who performed the calibration, intercomparison, or comparison; and

(5) Evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a qualified medical physicist.

(K) The handler shall make survey records and measurements required by this rule available upon request during an inspection.

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3701:1-67-04 Quality Management Program.

- (A) Each handler subject to the requirements in rules 3701:1-67-05, 3701:1-67-06, or 3701:1-67-10 of the Administrative Code shall develop, implement, and maintain a quality management program to provide high confidence that radiation will be administered as directed by the physician authorizing its use.

- (B) The quality management program shall address, as a minimum, the following specific objectives regarding written directives:
 - (1) A written directive must be dated and signed by a physician authorizing its use prior to the administration of radiation. If because of the patient's condition, a delay in the order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in the patient's record and a revised written directive is signed by an authorized user within forty-eight hours of the oral revision;
 - (2) The written directive must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions;
 - (3) A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the therapy equipment dose, or the next fractional dose; and
 - (4) The handler shall retain a copy of the written directive for seven years.

- (C) The handler shall develop, implement, and maintain written procedures to provide high confidence that:
 - (1) Prior to the administration of each course of radiation treatments, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;
 - (2) Each administration is in accordance with the written directive;
 - (3) The final plans of treatment and related calculations are in accordance with the respective written directives by:
 - (a) Checking both primary and secondary dose calculations to verify they are correct and in accordance with the written directive; and

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- (b) Verifying that the planned parameters are correctly transferred to the treatment charts;
- (4) Any unintended deviation from the written directive is identified, documented, evaluated and appropriate action is taken; and
- (5) The handler retains a copy of the procedures for administrations for the duration of the facility.

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3701:1-67-07 Calibration of Survey Instruments.

- (A) The handler shall ensure that the survey instruments used to show compliance with Chapter 3701:1-67 of the Administrative Code have been calibrated before first use, at intervals not to exceed twelve months, and following repair.
- (B) To satisfy the requirements of paragraph (A) of this rule, the handler shall ensure that the survey instruments are:
 - (1) Calibrated on all required scale readings up to 10 mSv (1000 mrem) per hour with an appropriate radiation source that is traceable to the “National Institute of Standards and Technology“ (NIST);
 - (2) Calibrated on at least two points on each scale to be calibrated. These points should be at approximately one-third and two-thirds of full-scale; and
- (C) To satisfy the requirements of paragraph (B) of this rule, the handler shall:
 - (1) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than ten per cent; and
 - (2) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than twenty per cent if a correction factor or graph is conspicuously attached to the instrument.
- (D) The handler shall retain a record of each calibration required in paragraph (A) of this rule for three years. The record shall include:
 - (1) A description of the calibration procedure; and
 - (2) A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.
- (E) The handler may obtain the services of individuals approved by the department to perform calibrations of survey instruments. Records of calibrations that contain information required by paragraph (D) of this rule shall be maintained by the handler.

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3701:1-67-12 Reports and Notifications of Misadministrations.

A handler shall report any misadministration resulting from intervention of a patient or human research subject in which the administration of therapeutic radiation equipment results, or will result in, unintended permanent functional damage to an organ or a physiological system as determined by a physician.

- (A) Other than misadministrations that result from intervention by a patient or human research subject, a handler shall report any event in which the administration of radiation from therapy equipment involves the wrong patient, wrong treatment, or wrong treatment site; and
 - (1) The calculated weekly delivered treatment differs from the weekly prescribed treatment by more than thirty per cent; or
 - (2) The calculated total delivered treatment differs from the total prescribed treatment by more than twenty per cent of the total prescribed dose; or
 - (3) The calculated total delivered treatment differs from the total prescribed treatment by more than ten per cent of the total prescribed dose for treatments consisting of three or fewer fractions; or
 - (4) The calculated total delivered treatment to critical organs differs from the treatment plan by a significant amount as determined by the prescribing physician.
- (B) Unintended deviations to the treatment plan which do not require notification to the department as required by paragraph (A) of this rule, shall be documented in the patient's chart, reported to the prescribing physician, and addressed internally within the therapy facility.
- (C) The handler shall notify the department by telephone no later than the next calendar day after the handler ascertains that a misadministration occurred.
- (D) The handler shall submit a written report to the department within fifteen days after the initial report of the misadministration. The written report must include:
 - (1) The handler or registrant name;
 - (2) The name of the prescribing physician;
 - (3) A brief description of the event;
 - (4) Why the event occurred;

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- (5) The effect, if any, on the individual who received the misadministration;
 - (6) Actions, if any, that have been taken, or are planned, to prevent recurrence; and
 - (7) Certification that the handler notified the individual, or the individual's responsible relative or guardian, and if not, why not.
- (E) The report shall not contain the individual's name or any other information that could lead to the identification of the individual.
- (F) The handler shall provide verbal and written notification of the misadministration to the referring physician no later than twenty-four hours after the initial notification. The handler shall also notify the individual who is the subject of the misadministration no later than twenty-four hours after the initial notification, unless the referring physician personally informs the handler either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The handler is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within twenty-four hours, the handler shall notify the individual as soon as possible thereafter. The handler may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the handler shall inform the individual or appropriate responsible relative or guardian that a written description of the event can be obtained from the handler upon request. The handler shall provide such a written description if requested.
- (G) Aside from the notification requirement, nothing in this section affects any rights or duties of handlers, registrants and physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relatives or guardians.
- (H) The handler shall retain a record of a misadministration in accordance with paragraph (I) of this rule. A copy of the record required shall be provided to the referring physician if other than the handler within fifteen days after discovery of the misadministration.
- (I) A handler shall retain a record of misadministrations reported for three years. The record must contain the following:
- (1) The handler or registrant's name and the names of the individuals involved;

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- (2) The social security number or other identification number, if one has been assigned, of the individual who is the subject of the misadministration;
- (3) A brief description of the event; why it occurred; the effect, if any, on the individual;
- (4) The actions, if any, taken or planned to prevent recurrence; and
- (5) Whether the handler or the registrant notified the individual, or the individual's responsible relative or guardian; and, if not, whether such failure to notify was based on guidance from the referring physician.